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Application No. 10/729,340
Amendment dated
Reply to Office Action of September 29, 2006

Docket No. NY-LUD 5793-US1-CIP

REMARKS

Entry of the amendment is requested, whereby claims 13, 58-60, 85, 86, 92 and 115 will be pending.

Claim 115 is new and is drawn to the subject matter which the Examiner concedes is enabled, at page 4, point 7 of the action.

Regarding point 3, the specification has been updated to the extent possible. The Examiner is well aware that 10/181,663 is not something that can be updated, since he is handling the case.

Claim 114 is canceled, rendering point 4 moot.

Claim 92 is presented in independent form, rendering point 5 moot and moving claim 92 to allowable status. Point 5 is moot.

The Examiner has rejected claims 58-60 under 35 U.S.C. § 112, second paragraph, as allegedly being vague and unclear. Applicants traverse.

The language of amended claim 58 has been approved by the USPTO. See, e.g., claim 20 of U.S. Patent No. 6,830,924. The language of the claim is perfectly clear. Claimed are compositions which contain peptides. The peptides must be at least 8 amino acids long and no more than 25 amino acids long. The amino acid sequence of the claimed peptide must be found in the reference sequences. Hence, while LLSHGAVIEV is encompassed by the claims, LCCCLCCSHGAVIEV is not. The second peptide is 8-25 amino acids in length, but it does not appear in the referenced proteins, whereas the first one does, and is. The metes and bounds of the claims are clear, and can be determined easily. The rejection is improper and should be withdrawn.

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Turning to the lack of enablement rejection of claims 58-60 (point 7), applicants traverse.

They point out again that given the finding in U.S. Patent No. 6,830,924, e.g., that a claim of this type is enabled, the presumption of enablement for claims 58-60 is even stronger. Beyond this, however, the Examiner has not made out a *prima facie* case of lack of enablement.

Black letter law clearly establishes that the fact that a claim is broad does not render it non-enabled. Nor does the fact that experimentation is required to determine what is and is not encompassed by the claims. The test is: would the amount of experimentation that is necessary be undue.

With respect to alleged lack of guidance, a specification need not teach, and preferably leaves out, that which the art already knows.

Example 21 of the specification, e.g., teaches how to test peptides for their ability to bind to HLA-A2 molecules and to stimulate CTLs. The test is presented in great detail. The reference protein and its sequence are provided.

Undoubtedly, not all peptides possible satisfying the structural parameters of the claim, will work. That, however, is not the end of the inquiry. The test is: would it require undue experimentation to determine those which will work? Applicants have shown that it is not. Assuming *arguendo* that the only 3 peptides which function as claimed are those that the Examiner concedes are enabled, then that is all the claim covers. Applicants need not disclose one, ten, fifty, or any additional peptides, once they have taught the art how to practice their invention. Indeed, they have.

The Examiner cites to Roitt and to U.S. Patent No. 5,840,839 in support of his rejection.

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Reliance on Roitt is interesting. The Examiner states that Roitt teaches that peptides 12-15 amino acids long are optional for MHC Class I binding. While applicants note that this is NOT in concordance with the field as a whole, let one assume that it is true.

The claims cover peptides 12-15 amino acids long. Further, ironically, the peptides the Examiner concedes are enabled are 10, 9, and 9 amino acids long. Clearly, Roitt is not definitive on this issue.

With respect to U.S. Patent No. 5,840,839, applicants do not disagree with the contention that not all peptides that bind to an HLA molecule will stimulate CTLs. They candidly admit this themselves, at page 20.

Regarding the '839 patent, it is noted that this patent is based on an application filed in 1996, which hardly makes it "state of the art" for 1999.

It is agreed that structure alone cannot be used as a "predictor" of what will function as a CTL stimulating peptide. That is what the '839 patent teaches. It also teaches how to test the peptides which satisfy structural requirements, to determine their functional attributes. So do applicants. Applicants have satisfied the enablement requirement, and the rejection should be withdrawn.

Turning next to the rejection at point 8, applicants point out that they have deleted "or part" in claim 13. Applicants, contrary to the Examiner's assertions, have identified a function of the claimed peptides. They are "cancer associated antigens," meaning they serve as indicators of the presence of cancer. The rest of the Examiner's position is not understood. The Examiner has not explained why the claim language is insufficient, and in fact, the rejection is self-contradictory.

For example, at page 7, lines 4-5, the Examiner states:

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"Claims 13, 58-60, 85, and 86 are drawn to genus of peptides comprising a fragment of SEQ ID N O: 32."

Then the Examiner states, at page 8:

"A description of a genus of full length proteins may be achieved by means of a recitation of a representative number of protein encoded by the corresponding <sic; the> ORFs, defined by nucleotide sequences, falling within the scope of the genus or a recitation of structural features common to the members of the genus, which features constitute a substantive portion of the genus."

It certainly seems to applicants that the claims are in accordance with the option set forth by the Examiner. In view of this compliance, the rejection is not proper, and should be withdrawn.

All issues have been addressed and resolved. Allowance of this application is believed proper and is urged.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-LUD 5793-US1-CIP (10815551) from which the undersigned is authorized to draw.

Dated: 12/19/06

Respectfully submitted,

By 

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Amendment in Response to Non-Final Office Action